UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,708	10/13/2005	Gudmundur G. Haraldsson	01526.400600	8684

5514 7590 03/27/2008

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
CUTLIFF, YATE KAI RENE	
ART UNIT	PAPER NUMBER
1621	
MAIL DATE	DELIVERY MODE
03/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,708	HARALDSSON ET AL.	
	Examiner	Art Unit	
	YATE K. CUTLIFF	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1-22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-22 are pending.

Terminal Disclaimer

2. The terminal disclaimer filed on November 8, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of February 11, 2003 for U.S. 6,518,049 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

3. Applicant's arguments, see the Amendment, filed November 8, 2007, with respect to the rejection(s) of claim(s) 1-4, 6, 7, 12-19, 21 and 22 under 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

4. Applicant's arguments with respect to the rejection of claims 1-22 under 35 U.S. C. 103(a) have been considered but are moot in view of the new ground(s) of rejection under 35 U.S. C. 103(a) in view of Haraldsson et al. (Journal of the American Oil Chemist Society, (1997), vol. 74, No. 11) (Haraldsson 1), Haraldsson et al. (Journal of the American Oil Chemist Society, (1997), vol. 74, No. 11), Brevik et al. ((Journal of the American Oil Chemist Society, (1997), vol. 74, No. 11) and JFS Envirohealth Limited (GB 2350610A) (JFS).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 2, 8-11, 15-19, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haraldsson et al. (Journal of the American Oil Chemist Society, (1997), vol. 74, No. 11), Brevik et al. ((Journal of the American Oil Chemist Society, (1997), vol. 74, No. 11) and JFS Envirohealth Limited (GB 2350610A) (JFS).

9. The rejected claims cover, inter alia, a process for separating ethyl or methyl ester fraction enriched in EPA (eicosapentaenoic acid, C20:5) and a free fatty acid fraction enriched in DHA (docosahexaenoic acid, C22:6) from a mixture of such

compounds that has been obtained by a direct esterification of fish oil free fatty acids with a ethanol or methanol using lipase, said process comprising the step of subjecting said mixture to molecular distillation.

Haraldsson et al. discloses a process for the direct esterification of a fish oil FFA with a lipase the can be immobilized Rhizomucor miehei (MML), at a temperature that is similar to the temperature of the ethanolysis process disclosed in the reference (20°C), to produce enriched in EPA (eicosapentaenoic acid) and a free fatty acid fraction enriched in DHA (docosahexaenoic acid). (see column 1, page 1552, first paragraph & column 2, page 1553, second paragraph). The reaction process used stoichiometric amounts of ethanol, with stoichiometric amounts meaning three molar equivalents of ethanol as based on glycerol, or one equivalent as based on the number of ester functions present in the glycerol backbone. (see column columns 1, second paragraph and column 2 second paragraph, page 1553). Tables 3-7 disclose the results from the Haraldsson et al. direct esterification of fish oil FFA with a lipase and concluded that the type of fish oil and extent of conversion are highly important parameters in controlling the degree of concentration, and that multi-step processes may offer highly enriched or pure EPA or DHA concentrates by carefully controlling the choice of starting oil and extent of conversion. Haraldsson et al. discloses a process for ethanolysis (alcoholysis) of fish oil and a process where the glyceride of fish oil can be hydrolyzed. (column 1, page 1553 and column 1 page 1552).

Haraldsson et al. fails to explicitly disclose the separation of the ethyl of methyl ester of the enriched EPA and enriched DHA products of direct esterification with a lipase by subjecting it to molecular distillation.

Brevik et al. discloses a process whereby EPA and DHA, having been concentrated by transesterification and containing acylglycerols, are separated from the saturated and monosaturated ethyl esters by short-path distillation (molecular distillation). (see column 2, second paragraph page 1426).

JFS discloses a process in Example 2, on page 11, where short path distillation used on the products of transesterification of the fatty acid ethyl esters containing EPA and DHA. Further, after short path distillation, the distillation product is subjected to a subsequent transesterification process and short path distillation. Each time these process steps occur, more of the ethyl esters of EPA and DHA concentrates are produced and removed, which results in a change in the EPA to DHA ratio in the concentrated mixture. (see Examples 1-3).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to a mixture of enriched EPA and enriched DHA by direct esterification as disclosed by Haraldsson et al. and subject the mixture to molecular distillation as disclosed by Brevik et al and JFS to separate the ethyl or methyl esters of the EPA and DHA, formed during the esterification process, and have a reasonable expectation of success.

One of ordinary skill in the art, at the time of the claimed invention, would have been motivated to use molecular distillation in order to optimize the process since JFS

demonstrates that each time EPA and DHA concentrates go thorough transesterification and short path distillation, new ethyl esters are produced and the concentrate mixture of EPA and DHA increases. Additonally, the EPA to DHA ratio in the mixture changes based on the starting ration of EPA to DHA in the concentrated mixture prior to transesterification.

Further, the dependent claims are drawn to work up and optimization of the final products. These limitations are deemed to be obvious absent a showing of unexpected results.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. *(In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) (1976). Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claims 3 - 7, 12 - 17, 20, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over unpatentable over Brevik et al. ((Journal of the American Oil Chemist Society, (1997), vol. 74, No. 11) JFS Envirohealth Limited (GB 2350610A) (JFS), and Haraldsson et al. (Journal of the American Oil Chemist Society, (1997), vol. 74, No. 11).

11. The rejected claims cover, inter alia, cover a process for treating a marine oil composition containing EPA and DHA as Cn alkyl esters of fatty acids (n = 2-18) to form (1): a Cn alkyl ester fatty acid fraction (n = 2-18) enriched in DHA as compared to the starting material and a Cm alkyl ester fatty acid fraction (m = 1-12; n > m) enriched in

EPA as compared to the starting material, or (2): a Cn alkyl ester fatty acid fraction (n = 2-18) enriched in both DHA and EPA as compared to the starting material and a Cm alkyl ester fatty acid fraction (m = 1-12; n > m) lower in both DHA and EPA as compared to the starting material comprising the step of reacting said marine oil composition with a Cm alcohol (m= 1-12; n>m) in the presence of a lipase catalyst under essentially organic solvent free conditions, and separating the fraction by molecular distillation.

Applicant is directed to the description of Brevik et al. in paragraph 8 above. Further, in Table 4 of Brevik et al. discloses a composition containing EPA and DHA as Cn alkyl esters of fatty acids (n= 2-18). According to Brevik et al. the products of Table 4 can be converted to ethyl esters enzymatically. (see column 1, page 1428, paragraph 1).

JFS, in Example 1 discloses a marine oil composition containing EPA and DHA as Cn alkyl esters of fatty acids after short path distillation (molecular distillation). Further, composition product of Example 1 is subjected to transesterification in the presence of a Cm alcohol and a lipase and separated by soft path distillation. Example 3 of JFS discloses a process where the product from Example 2 goes through transesterification to produce an enriched EPA and enriched DHA fraction where the DHA is lower than in the starting material of Example 1.

Brevik et al. and JFS fails to disclose the use of Rhizomucor miehei lipase, the temperature ranges, the ratio of alcohol to alkyl ester and that the C2-18 alkyl ester is a hexyl ester.

Haraldsson et al. discloses the claimed lipase, temperature ranges and alcohol to alkyl ester. Applicant is directed to paragraph 8 above. Haraldsson et al. discloses an ethanolysis process for fish oil on page 1553 and scheme 2 shows that the products contain Cn alkyl esters of fatty acids. Further, with regard to the alkyl ester being a hexyl ester, Haraldsson discloses altering the alcohol in the direct esterification process to a hexanol with success. Therefore, one of ordinary skill in the art would have been motivated to alter tweak an earlier transesterification process (or esterification process), that formed the marine oil composition and use a hexanol that process to produce the hexyl ester.

For the reasons set forth above in paragraphs 9 and 10, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat a marine oil composition, which could be any crude untreated fish oil triglyceride, or fish oil having gone through esterification or transesterification process, as suggested by Brevik et al, JFS and Haraldsson et al.; to form an enriched fraction of EPA and enriched fraction of DHA where the fractions of EPA and DHA are higher or lower than the EPA and DHA n the starting marine oil composition. Further, it would have been obvious to subject that lipase catalyzed product to one or more molecular distillation steps as suggested by Brevik et al. and JFS to produce desired fraction.

Therefore, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as clamed by known methods with no change in their respective functions, and the combination would have yielded

predictable results to one of ordinary skill in the art at the time of the invention. KSR International Co. v. Teleflex Inc., 550 U.S. ___, 82 USPQ2d 1385 (U.S. 2007).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272 - 0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yaté K. Cutliff
Patent Examiner
Group Art Unit 1621
Technology Center 1600

/Samuel A. Barts/
Primary Examiner
Art Unit 1621